REMARKS

Claims 1-10 were pending in the application at the time the Office Action was mailed. Claims 1-10 were rejected. Claims 1, 2, 5, 6, and 7 have been amended, claim 10 has been canceled, and no new claims have been added herein. Therefore, claims 1-9 remain pending in the application.

Information Disclosure Statement

According to the Office Action, the information disclosure statement (IDS) filed 1/5/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MMPEP §609 because the final listed reference is not a proper citation. Applicants are working to obtain the date of the reference and will submit this missing element as soon as it is obtained.

Claim Objections

Claim 1 was objected to for reciting a typographical error (i.e., "(5217G>A)"). Claim 1 has been amended to correct this typographical error.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-7 and 9-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Panguluri et al. (Human Genetics (1999) 105:28-31; provided in IDS). According to the examiner:

> Panguluri et al. teach a method for analyzing a biological sample comprising (a) obtaining a biological sample from a subject; and (b) analyzing the sample for the presence of a genetic polymorphism or mutation that is an adenine to guanine transition at position 5217 in the BRCA1 gene. The Examiner asserts that since Panguluri et al. teach analysis of the entire coding region of the BRCA1 gene from 45 African American breast cancer patients (p. 28), every single position within the entire coding region of the gene was analyzed for the presence of a genetic polymorphism or mutation, including position 5217. The instant claims do not require that a particular variant sequence be detected, only that the sample is analyzed for the presence of the polymorphism or mutation. Since Panguluri et al. analyzed the entire coding region for any irregularities that were present, the teachings of Panguluri et al. anticipate the claim.

Applicants respectfully disagree with this rejection because each of the claims include at least one element that is not described in Panguluri et al. For example, regarding independent claim 1 (from which the remaining claims depend) which recites "analyzing the sample for the presence of an adenine to guanine transition at position 5217 in the *BRCA1* gene (5217 A>G)...," Panguluri et al. fails to teach obtaining a sample from an African American subject and analyzing the sample for the presence of a mutation or polymorphism at position 5217 in the *BRCA1* gene, let alone an adenine to guanine transition at position 5217. Instead, Panguluri et al. teaches examining the entire *BRCA1* coding and flanking intron regions by single stranded conformation polymorphism analysis followed by sequencing of variant bands "to determine the spectrum of germline *BRCA1* mutations..." There is no mention in Panguluri et al. of position 5217 and therefore no description of analyzing a sample for the presence of an adenine to guanine transition at position 5217 in the *BRCA1* gene as recited in the claims.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claim Rejections Under 35 U.S.C. § 103

Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Panguluri et al. in view of Livak et al. (U.S. Patent 5538848). According to the Office Action:

> Panguluri et al. do not conduct a real-time PCR amplification.
>
> Livak et al. teach real time PCR methods and teach that an advantage of using such a method is the ability to know whether PCR is occurring while the cycling reactions are taking place, minimizing possible cross-contamination, and monitoring the efficiency of amplification reaction to be evaluated, which can indicate where reaction inhibitors are present in the sample (Col. 1, lines 30-52).
>
> Thus, at the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to have modified the methods taught by Panguluri et al. so as to have used the real-time PCR methods taught by Livak et al. One would have been motivated to use the real time PCR methods taught by Livak et al. in place of the conventional PCR taught by Panguluri et al. in order to have provided a means for monitoring the PCR progression while the reaction was

taking place, in order to monitor for the presence of inhibitors, for example. In view of the teachings of the prior art, the claimed invention is prima facie obvious.

Applicants submit that the combination of references does not teach all the claim limitations present in independent claim 1 (and thus the remaining claims which depend from claim 1). For example, neither reference teaches "analyzing the sample for the presence of an adenine to guanine transition at position 5217 in the *BRCA1* gene (5217 A>G)...," Panguluri et al. was discussed above, and Livak et al. does not mention a) a method for analyzing a biological sample from an African American woman for the presence of a polymorphism or mutation associated with breast cancer, or b) analyzing the sample for the presence of an adenine to guanine transition at position 5217 in the *BRCA1* gene (5217 A>G). Instead, Livak et al. teaches detecting nucleic acid amplification using a self-quenching fluorescence probe.

Based on the foregoing, applicants submit that the cited references do not render the present invention obvious within the meaning of 35 U.S.C. 103. Under this section, the prior art references when combined must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants submit that none of the references cited above, nor the combination of, teach all the limitations of the present and amended claims, nor do the references suggest modifying their teachings to arrive at applicant's invention.

For the foregoing reason, withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-10 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. According to the Office Action, the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully disagree with this rejection, and submit that the specification does indeed provide support for an association between the nucleotide present at position 5217 in the *BRCA1* gene and the risk of breast cancer development in African-American women. See, for example, TABLE 3 on page 9 which shows that mutation 5217A>G was found in an African-American family with breast cancer but not in a control population of 50 African-American women not having breast cancer. Additionally, filed herewith is a 1.132 Declaration signed by a co-inventor (Dr. Baumbach-Reardon) further supporting that there is an association between the nucleotide present at position 5217 in the *BRCA1* gene and the risk of breast cancer development in African American women.

Accordingly, withdrawal of these rejections is respectfully requested.

CONCLUSION

Applicants have made every effort to present claims which overcome the Examiner's assertions, and it is believed that all claims are now in condition for allowance. No new matter has been added by virtue of this amendment. If there are any remaining issues or the Examiner believes that a telephone conversation with the Applicants' attorney or agent would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at the telephone number shown below.

This response is being filed with a two month retroactive petition for extension of time and the appropriate fees. Although Applicants believe that no further extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any further extensions of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,

AKERMAN SENTERFITT

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